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October 15, 2018

VIA ECF
The Honorable Colm F. Connolly
United States District Court
J. Caleb Boggs Federal Building
844 North King Street, Room 4124
Wilmington, DE 19801-3570

Re: ***Pharmcyclics LLC et al. v. Fresenius Kabi USA, LLC et al.*****, C.A. 18-192-CFC**
Pharmcyclics LLC et al. v. Shilpa Medicare Limited et al.**, C.A. 18-237-CFC**
Pharmcyclics LLC et al. v. Cipla Limited et al.**, C.A. 18-247-CFC**
Pharmcyclics LLC et al. v. Zydus Worldwide DMCC et al.**, C.A. 18-275-CFC**

Dear Judge Connolly:

We write on behalf of Defendants in the above-captioned cases regarding the following disputes that arose during negotiation of a Protective Order ("PO"): (1) Plaintiffs' use and cross-disclosure of one Defendant's proprietary information to other Defendants; and (2) access to designated information for a non-attorney responsible for supervising litigation on behalf of Cipla.

I. Plaintiffs Should Not Control Cross-Disclosure of Defendants' Confidential Information

Defendants seek a reasonable and narrowly tailored provision that would prohibit Plaintiffs from generally disclosing information designated Confidential by one Defendant to another Defendant absent the first Defendant's consent (*see* Paragraphs 19-20 of Exhibit A). Defendants' proposal allows outside counsel of record for all Defendants to be served with any submission filed with the Court containing any of Defendants' Confidential Information, and makes clear that any order issued by Your Honor that contains a Defendant's Confidential Information may likewise be served on all outside counsel of record for Defendants. Plaintiffs continue to seek an unfettered ability to disclose one Defendants' Confidential Information to another Defendants' outside counsel and experts, without limitation.

A. Plaintiffs Do Not Need the Ability to Cross-Disclose Defendants' Confidential Information

Plaintiffs have not articulated any basis, other than Plaintiffs' own convenience, to disclose one Defendant's Confidential Information to the other Defendants' outside counsel or experts. But Defendants' proposal ameliorates any alleged inconvenience to Plaintiffs by permitting disclosure of Confidential Information in Court submissions. Plaintiffs' proposal, in contrast, far exceeds the bounds of convenience and would improperly permit Plaintiffs to use one Defendant's Confidential Information against another Defendant.

Permitting Plaintiffs to do so would be unfair to the Defendants against which another Defendant's Confidential Information may be used for several reasons. *First*, Defendants' Confidential Information concerning their respective ANDA products is not relevant to the validity of Plaintiffs' patents. *Second*, when assessing whether a particular Defendant's ANDA product infringes, only that Defendant's ANDA is relevant. *See Bayer AG v. Elan Pharmaceutical Research Corp.*, 212 F.3d 1241, 1249 (Fed. Cir. 2000) ("[T]he focus of the infringement inquiry under 35 U.S.C. § 271(e)(2)(A) is on the product that will be sold after the FDA's approval of the ANDA"). Plaintiffs have acknowledged as

much by serving separate infringement contentions for each Defendant. *Third*, permitting Plaintiffs to use one Defendant's Confidential Information against another would prejudice Defendants because Defendants would have to address arguments based on evidence to which they had no previous access and which they have no way to independently investigate or corroborate. That in and of itself would be unfairly prejudicial and unwarranted, especially where Plaintiffs have provided no legitimate basis or need to disclose Defendants' Confidential Information except for Plaintiffs' own convenience.

B. Defendants Face Serious Risks Under Plaintiffs' Proposal

Defendants' proposal is necessary to protect each Defendant's Confidential Information from disclosure to its competitors. Plaintiffs do not dispute that details of Defendants' ANDA products are highly sensitive and confidential, particularly in these cases, which include patents directed to specific formulations and specific forms of the active pharmaceutical ingredients. Each Defendant—not Plaintiffs—is best positioned to gauge what, if any, of this information can safely be disclosed to others, even on an outside counsels' eyes only basis.[1]

Each Defendant will potentially compete with all others when marketing generic ibrutinib. And, to the extent the outcome of the case, and thus market entry, is determined on an infringement issue, each Defendant will be severely prejudiced if its Confidential Information is directly or indirectly used against another Defendant. The FTC has long recognized that "firms that gain approval before rival generic firms are able to sell their product sooner, and face fewer initial competitors." *See* David Reiffen & Michael R. Ward, GENERIC DRUG INDUSTRY DYNAMICS 7 (Fed. Trade Comm., Working Paper No. 248, Feb. 2002), *available at* https://www.ftc.gov/reports/generic-drug-industry-dynamics.

It is not enough, as Plaintiffs contend, to limit the disclosure of Defendants' Confidential Information to the other Defendants' outside counsel and experts who may be called upon to advise their respective clients regarding ANDA and litigation strategy vis-à-vis the other Defendants. Courts recognize that the inadvertent use or disclosure of confidential business information is a significant risk that is best addressed through a clearly drafted PO designed to avoid the risk of inadvertent disclosure—precisely what Defendants' proposal accomplishes.

C. Defendants' Proposal Is Consistent With Numerous Prior Protective Orders

Litigants in patent cases have agreed to provisions similar to Defendants' proposal to protect Defendants' Confidential Information. In the handful of cases known to Defendants in which this issue

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[1] During the meet and confer process, Plaintiffs stated that it would be unfair to allow Defendants to share information with each other, but preclude Plaintiffs from sharing Defendants' confidential information with other Defendants. This position is without merit. The Third Circuit has recognized that joint defense privilege protects "communications [that] are part of an on-going and joint effort to set up a common defense strategy." *Matter of Bevill, Bresler & Schulman Asset Mgmt.*, 805 F.2d 120, 126 (3d Cir. 1986); *see also In re Teleglobe Commc'ns Corp.*, 493 F.3d 345, 364-66 (3d Cir. 2007). Defendants' decision to share their own confidential information with each other in furtherance of a joint defense strategy in no way entitles Plaintiffs to disclose confidential information to other Defendants, even if only to outside counsel and experts. Moreover, Defendants' proposed protections against cross-disclosure will not prejudice Plaintiffs because Plaintiffs will have access to all of Defendants' Confidential Information.

has been disputed, courts have ruled in favor of defendants, stating in one such case that the court "sees efficiency in permitting each Defendant control over the disclosure of its confidential information to its direct competitors without unduly interfering with Plaintiffs ability to prosecute its case." D.I. 77, *Supernus Pharms., Inc. v. Actavis, Inc.*, No. 2:14-06102, ¶ 2 (D.N.J. Sept. 23, 2015) (Ex. B).[2]

II. Cipla's Non-Attorney Responsible for Managing This Litigation Should Have Access to Confidential Information Under the Protective Order

Cipla seeks a Stipulated PO that allows Cipla to designate a foreign, non-attorney to have access to Plaintiffs' Confidential Information. Plaintiffs have refused to allow Cipla to designate such a person, despite allowing another defendant, Zydus, to do so.

As the parties seeking to restrict access, Plaintiffs bear the burden of establishing good cause to justify precluding Cipla's non-attorney from accessing Confidential Information under the PO. *See Toshiba Samsung Storage Tech. Korea Corp. v. LG Elecs., Inc.*, No. 15-691-LPS-CJB, 2016 WL 447794, at *1 n.1 (D. Del. Feb. 4, 2016). "Good cause is established on a showing that disclosure will work a clearly defined and serious injury to the party seeking closure." *Publicker Indus., Inc. v. Cohen*, 733 F.2d 1059, 1071 (3d Cir. 1984). Plaintiffs must make "a particular and specific demonstration of fact, as distinguished from stereotyped and conclusory statements." *See Cipollone v. Liggett Grp., Inc.*, 785 F.2d 1108, 1121 (3d Cir. 1986) (citation omitted). Plaintiffs cannot do so here.

Plaintiffs' reason for refusing to allow access to Cipla's in-house employee is that she is not an attorney. This does not establish "good cause" because it does not clearly define a serious injury and relies on a conclusory and stereotyped allegation of harm. Moreover, the following factors mitigate against Plaintiffs' proposed restriction: (1) Cipla's designee will be bound by the PO, subject to this Court's jurisdiction for purposes of the PO, and will be supervised by attorneys bound by the PO, thereby providing more safeguards to Plaintiffs' Confidential Information than with Zydus's designee, who will lack attorney oversight; (2) Cipla's non-attorney designee is not involved in competitive decision-making activities or FDA communications regarding ibrutinib; (3) Cipla's intended designee has received confidential information under protective orders in this and other districts; and (4) Plaintiffs' proposed restrictions will prejudice Cipla because Cipla's non-attorney designee has the most intimate day-to-day knowledge of the ibrutinib project, while Cipla's intended attorney designees have supervisory roles for this and other litigations and would be unable take on day-to-day management of this litigation. Finally, the proposed PO has a mechanism for Plaintiffs to make a particularized objection to Cipla's specific non-attorney designee employee. That mechanism should be employed rather than categorically precluding designation of Cipla's non-attorney designee.

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For the foregoing reasons, Defendants respectfully request that the Court adopt Defendants' proposed Protective Order.

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[2] *See also* D.I. 67, *In re Fetzima*, No. 2:17-10230, ¶ 5 (D.N.J. May 21, 2018); D.I. 65, *Astellas Pharma Inc. v. Actavis Elizabeth LLC*, No. 16-cv-905, ¶ 3 (D. Del. July 20, 2017); D.I. 71, ¶ 16, *AstraZeneca LP v. Sigmapharm Labs., LLC*, 15-cv-1000 (D. Del. April 26, 2016).

Respectfully,

/s/ Dominick T. Gattuso

Dominick T. Gattuso (#3630)

Enclosures

cc: All Counsel of Record Via Electronic Mail

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PHARMACYCLICS LLC and JANSSEN BIOTECH, INC., Plaintiffs, v. FRESENIUS KABI USA, LLC and FRESENIUS KABI ONCOLOGY LIMITED, Defendants.	)	C.A. No. 18-192 (CFC)
PHARMACYCLICS LLC, and JANSSEN BIOTECH, INC., Plaintiffs, v. SHILPA MEDICARE LIMITED, SUN PHARMA GLOBAL FZE and SUN PHARMACEUTICAL INDUSTRIES LTD., Defendants.	)	C.A. No. 18-237 (CFC)
PHARMACYCLICS LLC and JANSSEN BIOTECH, INC., Plaintiffs, v. CIPLA LIMITED and CIPLA USA INC., Defendants.	)	C.A. No. 18-247 (CFC)

PHARMACYCLICS LLC and JANSSEN BIOTECH, INC., Plaintiffs, v. ZYDUS WORLDWIDE DMCC, CADILA HEALTHCARE LIMITED, TEVA PHARMACEUTICALS USA, INC., SANDOZ INC. and LEK PHARMACEUTICALS D.D., Defendants.	)	C.A. No. 18-275 (CFC)

RULE 7.1.1 STATEMENT

Pursuant to District of Delaware Local Rule 7.1.1, Defendants in the above-captioned action hereby certify that they have engaged in reasonable efforts, including by electronic and telephonic means, to reach agreement with Plaintiffs on the matters concerning the parties' proposed Protective Order. The parties were unable to reach agreement.

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